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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,449	03/28/2005	Kazuyuki Yamane	10936-84	8257
24256 7590 12/14/2007 DINSMORE & SHOHL, LLP 1900 CHEMED CENTER 255 EAST FIFTH STREET CINCINNATI, OH 45202			EXAMINER TOSCANO, ALICIA	
			ART UNIT 1796	PAPER NUMBER
			MAIL DATE 12/14/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/529,449	<b>Applicant(s)</b> YAMANE ET AL.	
	<b>Examiner</b> Alicia M. Toscano	<b>Art Unit</b> 1796	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,5,7,10,11,17,18 and 21-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5,7,10,11,17,18 and 21-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 5, 7, 10 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Shinoda (US 5247013).

The high molecular weight aliphatic polyester of claim 1 is viewed as a product-by-process claim and hence the methods they are created by are not pertinent, unless applicant can show a different product is produced.

Shinoda discloses polyesters formed from glycolic acid (Column 1 line 23) having a MW of 155400 and PDI of 3.7 (Table 2 Ex 11, wherein  $MW = Mn \cdot PDI$ ), meeting the compositional elements of the above claims.

3. Claims 1, 5, 7, 10 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsumoto (JP 2001/323056).

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Masumoto includes elements as previously set forth in the action dated 6/4/07.

See comments below.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 11, 17, 18, 23, 24, 25, 26, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto.

Masumoto includes elements as previously set forth in the action dated 6/4/07.

See comments below.

5. Claims 1, 5, 7, 10-11, 17, 18 and 21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonsignore in view of Matsumoto.

Bonsignore and Masumoto include elements as previously set forth in the action dated 6/4/07. See comments below.

### ***Conclusion***

### ***Response to Arguments***

6. Applicant's arguments filed 5/2/07 have been fully considered but they are not persuasive. Applicant continues the arguments that the solution specific viscosity is evidence that Matsumoto does not meet the chain lengthening requirements of the

claims. Applicant hypothesizes that a decomposition reaction may have occurred upon end capping the polymer, resulting in a lower solution specific viscosity when one would expect a higher viscosity. Applicant argues Matsumoto demonstrates that only the endgroups of the polymer are endcapped and a chain lengthening reaction does not occur and that the burden is on the Examiner to show that a prior art reference discloses all of the limitations necessary to inherently result in the product. Applicant argues one of ordinary skill would recognize that the reaction conditions of Matsumoto are such that the whole amount of oxazoline compound does not react. In regards to Bonsignore, Applicant argues there is no evidence of record supporting the Examiner's assertion that the molecular weight ranges as disclosed for polylactic acid are applicable to polyglycolic acid.

Examiner disagrees. As stated in each of the past actions dated 6/4/07 and 9/12/07, Applicant's arguments and calculations relating to the specific viscosity are not convincing. When Matsumoto end caps the polymer, the molecular weight must increase. There is no disclosure, evidence or scientific reason that the molecular weight would decrease. Thusly, since Matsumoto discloses a decrease in specific viscosity the Examiner believes that the different interaction between the solution and newly endcapped polymer must affect the viscosity readings. Matsumoto is using the specific viscosity readings to further compare the hydrolysis rate of the polymers when subjected to hot water. Matsumoto is not concerned with the molecular weight or a molecular weight increase to prove end capping has occurred. Matsumoto relies on carboxyl equivalents as proof endcapping occurs. For these reasons the Examiner can

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not draw clear conclusions on Matsumoto's examples. There is no way to know what the MW difference is when comparing 2 specific viscosities. That only the carboxyl groups are terminated and the MW has not increased is only speculation since Masumoto does not disclose stopping the reaction prior to completion. Applicants composition and reaction are identical to Masumoto as such the Examiner believes that all of the limitations necessary to show the inherency of the MW have been addressed and as such the composition of Masumoto must inherently increase in MW. It is unclear why Applicant believes that one of ordinary skill would not recognize that the reaction conditions would not result in Applicant's claimed product. Evidence to the contrary is requested.

Regarding Bonsignore, the Examiner put forth that it is recognized in the art that polyglycolic and polylactic acid polymers are recognized as functional equivalents, and as such one would use the MW disclosed by Matsumoto for polylactic acid if one was to use polyglycolic acid. The motivation is proper and the rejection stands.

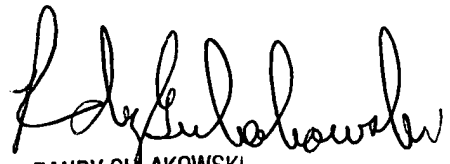
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia M. Toscano whose telephone number is 571-272-2451. The examiner can normally be reached on Monday to Friday 8:30 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on 571-272-1302. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMT



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